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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,532	05/02/2002	Harry B. Gray	CIIT1490-3	6210

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05/03/2005

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EXAMINER

LUM, LEON YUN BON

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/031,532	Applicant(s) GRAY ET AL.	
	Examiner Leon Y. Lum	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-35 is/are rejected.
- 7) ☒ Claim(s) 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 08 February 2005 is acknowledged and has been entered.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Claim Objections

3. Claim 29 is objected to because of the following informalities: The claims seems to be missing the phrase "consisting of" or "comprising of" between the terms "group" and "[Ru(phen)₂dppz]²⁺" in line 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 21-22 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 21-22 recite the limitations "said substrate moiety" and "the substrate moiety" in line 1 of claim 21 and line 2 of claim 22. There is insufficient antecedent basis for this limitation in the claim. The parent claim, claim 20, recites a "substrate molecule" in lines 3-4. However, there is no recitation of the instant limitations. Is the substrate moiety a part of the substrate molecule?

7. Claim 28 recites the limitation "said $\text{RU}(\text{bpy})_3^{2+}$ " in line 1. There is insufficient antecedent basis for this limitation in the claim. The parent claim, claim 27, does not recite a complex.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 20-28, 31-34, and 37 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Wilker et al (Angew. Chem. Int. Ed., 1999).

In the instant claim, Wilker et al teach the detection of a high valent heme believed to be a catalytic intermediate in the oxygenation reactions of cytochrome P450 (i.e. target biomolecule), by tethering a Ru photosensitizer to the protein substrate ethylbenzene, and reacting the Ru-EB complex (i.e. sensitizer-linked substrate molecule) with cytochrome P450 to generate an oxidized state of the enzyme (i.e. determining the presence of the complex to detect the target biomolecule), wherein spectroscopic changes via absorbance measurements is the detection means (i.e. irradiating the complex). See page 90, left column; page 91, left column, 1st-2nd paragraphs; and Figures 1 and 3 and caption.

With regards to claims 21, 27-28, and 32, Wilker et al teach that the Ru photosensitizer is $[Ru(bpy)_3]^{2+}$ and is linked through a hydrocarbon chain to a species with high affinity for the P450 heme pocket. See page 90, left column, 3rd paragraph.

With regards to claim 37, Wilker et al teach that addition of excess camphor (i.e. agent of interest) to (Ru-EB)-P450 displaces the Ru-linked substrate, as judged by an increased contribution of the slower luminescence decay process. See page 91, left column, 1st paragraph.

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10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 20-22, 26, 31, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Atta et al (US 5,478,729).

In the instant claim, Van Atta et al teach a competitive homogenous assay, wherein the extent of binding can be determined by using a fluorescence-labeled modified analyte (i.e. sensitizer-linked substrate molecule) and a quencher-labeled antibody (i.e. target biomolecule), and wherein the signal is inversely related to the extend of binding and directly related to the amount of analyte (i.e. agent of interest) present in the sample. See column 18, lines 31-36. In addition, Van Atta et al teach that members of a specific binding pair can be ligand and receptor. See column 4, lines 58-60. Furthermore, Van Atta et al teach that the label can be a photosensitizer, wherein the label can produce a detectable signal by electromagnetic radiation. See column 5, lines 32-38 and lines 56-61.

With respect to claim 31, Van Atta et al teach a linking group between the label and binding member. See column 6, lines 15-25.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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15. Claims 23-25 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Atta et al (US 5,478,729) in view of Gelboin et al (US 6,060,253).

Van Atta et al reference has been disclosed above, but fail to teach that the target biomolecule is cytochrome P450.

Gelboin et al teach cytochrome P450 enzyme as an analyte in an immunoassay, in order to identify enzymes that metabolize drugs or a carcinogen. See column 1, lines 10-28 and column 12, lines 15-28.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Van Atta et al with cytochrome P450 enzyme as an analyte in an immunoassay, as taught by Gelboin et al, in order to identify enzymes that metabolize drugs or a carcinogen. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including cytochrome P450 as a target biomolecule, as taught by Gelboin et al, in the method of Van Atta et al, since Van Atta et al teach immunoassays to detect a target biomolecule, and cytochrome P450 is one type of biomolecule that can be detected in an immunoassay.

16. Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Atta et al (US 5,478,729) in view of Ullman et al (US 6,406,913 B1).

Van Atta et al reference has been disclosed above, but fails to teach that the photosensitizer is $\text{Ru}(\text{bpy})_3^{2+}$.

Ullman et al teach $\text{Ru}(\text{bpy})_3^{2+}$, in order to provide a dye that has high fluorescent quantum yields. See column 28, lines 40-45.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Van Atta et al with $\text{Ru}(\text{bpy})_3^{2+}$, as taught by Ullman et al, in order to provide a dye that has high fluorescent quantum yields. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including $\text{Ru}(\text{bpy})_3^{2+}$, as taught by Ullman et al, in the method of Van Atta et al, since Van Atta et al teach photosensitizers in assays, and the $\text{Ru}(\text{bpy})_3^{2+}$ of Ullman et al is one type of sensitizer that can be used in an assay.

17. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilker et al (Angew. Chem. Int. Ed., 1999) in view of Barton (US 5,157,032).

Wilker et al reference has been disclosed above, but fails to teach that said photosensitizer is $[\text{Ru}(\text{phen})_2(\text{dppz})]^{2+}$.

Barton reference teaches $[\text{Ru}(\text{phen})_2(\text{dppz})]^{2+}$, in order to provide a non-radioactive luminescent DNA probe for assay systems. See column 45, lines 12-21.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Wilker et al with $[\text{Ru}(\text{phen})_2(\text{dppz})]^{2+}$, as taught by Barton, in order to provide a non-radioactive luminescent DNA probe for assay systems. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including $[\text{Ru}(\text{phen})_2(\text{dppz})]^{2+}$, as taught by Barton, in the method of Wilker et al, since Wilker et al teach labels for assays, and the $[\text{Ru}(\text{phen})_2(\text{dppz})]^{2+}$ of Barton is one type of label that can be used in an assay.

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18. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Atta et al (US 5,478,729) in view of Barton (US 5,157,032).

Van Atta et al reference has been disclosed above and additionally teaches that labels can be radiolabels (see column 5, lines 35-36), but fails to teach that said photosensitizer is $[\text{Ru}(\text{phen})_2(\text{dppz})]^{2+}$.

Barton reference teaches $[\text{Ru}(\text{phen})_2(\text{dppz})]^{2+}$, in order to provide a non-radioactive luminescent DNA probe for assay systems. See column 45, lines 12-21.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Van Atta et al with $[\text{Ru}(\text{phen})_2(\text{dppz})]^{2+}$, as taught by Barton, in order to provide a non-radioactive luminescent DNA probe for assay systems. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including $[\text{Ru}(\text{phen})_2(\text{dppz})]^{2+}$, as taught by Barton, in the method of Van Atta et al, since Van Atta et al teach labels for assays, and the $[\text{Ru}(\text{phen})_2(\text{dppz})]^{2+}$ of Barton is one type of label that can be used in an assay.

19. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilker et al (Angew. Chem. Int. Ed., 1999) in view of Wang et al (US 5,696,157).

Wilker et al reference has been disclosed above, but fails to teach that the photosensitizer is a 7-coumarin molecule.

Wang et al teach a 7-aminocoumarin as a fluorescent label to prepare fluorogenic substrates for enzymes, in order to provide excitation in the ultraviolet and blue to blue-green emission spectra. See column 1, lines 20-32.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Wilker et al with a 7-aminocoumarin as a fluorescent label to prepare fluorogenic substrates for enzymes, as taught by Wang et al, in order to provide excitation in the ultraviolet and blue to blue-green emission spectra. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a 7-aminocoumarin, as taught by Wang et al, in the method of Wilker et al, since Wilker et al teach labeling of enzyme substrates, and the 7-aminocoumarin of Wang et al is capable of labeling enzyme substrates.

20. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Atta et al (US 5,478,729) in view of Wang et al (US 5,696,157).

Van Atta et al reference has been disclosed above, but fails to teach that the photosensitizer is a 7-coumarin molecule.

Wang et al teach a 7-aminocoumarin as a fluorescent label to prepare fluorogenic substrates for enzymes, in order to provide excitation in the ultraviolet and blue to blue-green emission spectra. See column 1, lines 20-32.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Van Atta et al with a 7-aminocoumarin as a fluorescent label to prepare fluorogenic substrates for enzymes, as taught by Wang et al, in order to provide excitation in the ultraviolet and blue to blue-green emission spectra. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a 7-aminocoumarin, as taught by Wang

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et al, in the method of Van Atta et al, since Van Atta et al teach labeling of receptors, and the 7-aminocoumarin of Wang et al is capable of labeling enzyme substrates, which is a type of receptor.

21. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Atta et al (US 5,478,729) in view of Goodbody et al (US 5,569,745).

Goodbody et al teach an alkyl chain, in order to couple two compounds without adversely affecting the functions of either compound. See column 4, lines 24-33.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Van Atta et al with an alkyl chain, as taught by Goodbody et al, in order to couple two compounds without adversely affecting the functions of either compound. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including an alkyl chain, as taught by Goodbody et al, in the method of Van Atta et al, since Van Atta et al teach conjugates of biological molecules and metal sol labels (see column 5, line 48), and the alkyl chain of Goodbody et al is linked between a peptide and metal chelate, which is an example of a conjugation between a biological molecule and metal particle.

22. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Atta et al (US 5,478,729) in view of Gelboin et al (US 6,060,253) as applied to claims 20 and 33 above, and in further view of Thirugnanam (US 5,506,251).

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Van Atta et al and Gelboin et al references have been disclosed above, but fail to teach that said substrate is imidazole.

Thirugnanam reference teaches imidazole, in order to provide a cytochrome p450 inhibitor. See column 1, lines 35-43.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Van Atta et al and Gelboin et al with teaches imidazole, as taught by Thirugnanam, in order to provide a cytochrome p450 inhibitor. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including imidazole, as taught by Thirugnanam, in the method of Van Atta et al and Gelboin et al, since Van Atta et al and Gelboin et al teach substrates that bind to cytochrome P450, and the imidazole of Thirugnanam is one type of substrate that can bind to cytochrome P450.

23. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilker et al (Angew. Chem. Int. Ed., 1999) in view of Wang et al (US 5,696,157) as applied to claim 30 above, and further in view of Leung et al (Bioorganic & Medicinal Chemistry Letters, 1999).

Wilker et al and Wang et al references have been disclosed above, but fail to teach that the photosensitizer is a 7-, substituted coumarin molecule conjugated to nitric oxide synthase.

Leung et al teach a 7-amino-4-methyl-6-sulfocoumarin-3-acetic acid fluorescent dye, in order to enhance fluorescence quantum yields. See page 2230, 1st paragraph.

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It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Wilker et al and Wang et al with a 7-amino-4-methyl-6-sulfocoumarin-3-acetic acid fluorescent dye, as taught by Leung et al, in order to enhance fluorescence quantum yields. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a 7-amino-4-methyl-6-sulfocoumarin-3-acetic acid fluorescent dye, as taught by Leung et al, in the method of Wilker et al and Wang et al, since Wilker et al and Wang et al teach labeling of protein substrates with a 7-aminocoumarin, and the 7-amino-4-methyl-6-sulfocoumarin-3-acetic acid fluorescent dye of Leung et al is one type of 7-aminocoumarin.

24. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Atta et al (US 5,478,729) in view of Wang et al (US 5,696,157) as applied to claim 30 above, and further in view of Leung et al (Bioorganic & Medicinal Chemistry Letters, 1999).

Van Atta et al and Wang et al references have been disclosed above, but fail to teach that the photosensitizer is a 7-, substituted coumarin molecule conjugated to nitric oxide synthase.

Leung et al teach a 7-amino-4-methyl-6-sulfocoumarin-3-acetic acid fluorescent dye, in order to enhance fluorescence quantum yields. See page 2230, 1st paragraph.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Van Atta et al and Wang et al with a 7-amino-4-methyl-6-sulfocoumarin-3-acetic acid fluorescent dye, as taught by Leung et al, in order

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to enhance fluorescence quantum yields. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a 7-amino-4-methyl-6-sulfocoumarin-3-acetic acid fluorescent dye, as taught by Leung et al, in the method of Van Atta et al and Wang et al, since Van Atta et al and Wang et al teach labeling of protein substrates with a fluorescent dye, and the 7-amino-4-methyl-6-sulfocoumarin-3-acetic acid fluorescent dye of Leung et al is one type of 7-aminocoumarin.

Allowable Subject Matter

25. Claim 36 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

26. The following is a statement of reasons for the indication of allowable subject matter: Claim 36 is directed to structures of a conjugate, wherein the conjugate is a dipeptide amide linked to a specific coumarin molecule, and wherein the coumarin label and dipeptide amide are attached through a linker. The prior does not teach the claimed structures. The prior art does teach coumarin molecules linked to structures that include the dipeptide amide structure, but the specific linking structure claimed is not taught by the prior art as linking the coumarin molecules and dipeptide amide.

Response to Arguments

27. On page 8 of the Remarks, Applicants stated that a new declaration was filed on May 2, 2002. However, there is no record of the said declaration in the file. With regards to the PTO-issued Notice of Acceptance on July 11, 2002 and Applicants' statement that "all the items in the application were acceptable", this notice does not indicate whether the declaration is proper, but simply that a declaration has been submitted. Therefore, the requirement for Applicants to supply a proper declaration per the previous Office Action is maintained.

28. On pages 8-9, with regards to the rejection of claims 20 and 37 under 35 U.S.C. 102(a) anticipated by Wilker et al, Applicants contend that Wilker et al fail to disclose a method for detecting a target biomolecule or the modulating agent of interest using spectroscopic methods.

Applicant's arguments have been fully considered but they are not persuasive. As indicated in the rejection supra, Wilker et al teaches that conjugation of an Ru label to cytochrome P450 is performed in order to detect the high-valent heme (page 90, left column, 1st paragraph). Cytochrome P450 is considered to be the target biomolecule since it is detected using a label and the reference therefore anticipates the limitation of detecting a target biomolecule. In addition, Wilker et al detect absorption changes when camphor displaces Ru-EB from the (Ru-EB)-P450 complex. The absorption detection anticipates the spectroscopic limitation and since the (Ru-EB)-P450 complex is broken

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by camphor and causes a change in signal, the camphor is considered to be the modulating agent of interest. Therefore, Wilker et al teach all the limitations of claims 20 and 37 and anticipates the claims.

29. Applicant's arguments with respect to claims 21-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

30. Claims 20-35 are rejected.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

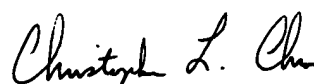
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y Lum
Patent Examiner
Art Unit 1641



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5/1/05